

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1 NAME OF THE MEDICINAL PRODUCT

Uniroid-HC

Hydrocortisone 5 mg / cinchocaine hydrochloride 5 mg suppositories

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains:

Hydrocortisone 5 mg and cinchocaine hydrochloride 5 mg

For the full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Suppositories.

An off-white, odourless, smooth, suppositories.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

Uniroid-HC Suppositories are indicated for use in the treatment of internal haemorrhoids for the short term relief of pain, irritation and associated pruritus ani.

#### 4.2 Posology and method of administration

##### Posology

##### *Adults*

Treatment with Uniroid-HC Suppositories should be limited to seven days. Patients should be advised to return to their doctor if the condition persists beyond this time.

Directions for use and dosage schedule:

Peel away the foil and insert a suppository as far as possible into the anus.

One suppository to be inserted twice a day (morning and evening) and after each bowel movement, or as prescribed by the doctor.

The suppositories may be used separately or concurrently with the ointment.

##### *Elderly patients*

Dosage modifications are not required in the elderly.

##### *Paediatric population*

Uniroid-HC Suppositories are not recommended for use in children under 12 years of age unless directed by a doctor.

##### Method of administration

For rectal use only

### **4.3 Contraindications**

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

This product is contraindicated in tuberculosis, anal thrush and most viral lesions of the skin including herpes simplex, vaccinia and varicella.

### **4.4 Special warnings and precautions for use**

Recurrent or prolonged application may increase the risk of contact sensitisation particularly to cinchocaine.

As with all preparations containing topical steroids, the possibility of systemic absorption should be considered. In particular, long-term continuous therapy should be avoided in infants. Adrenal suppression can occur even without occlusion.

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR).

### **4.5 Interaction with other medicinal products and other forms of interaction**

Co-treatment with CYP3A inhibitors, including cobicistat-containing medicinal products, is expected to increase the risk of systemic side-effects.

The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

### **4.6 Fertility, pregnancy and lactation**

#### Pregnancy

In pregnant animals, administration of corticosteroids can cause abnormalities of foetal development. The relevance of this finding to human beings has not been established. However, topical steroids should not be used extensively in pregnancy, i.e. in large amounts or for long periods.

#### Breastfeeding

Hydrocortisone may pass into human breast milk. Given the possible maternal systemic absorption and lack of data, Uniroid-HC Suppositories should preferably not be used during lactation unless the potential benefits to the mother outweigh the potential risks, including those to the breastfed child.

### **4.7 Effects on ability to drive and use machines**

Uniroid-HC Suppositories have no or negligible influence on the ability to drive and use machines.

### **4.8 Undesirable effects**

The frequencies of adverse events are ranked according to the following convention: very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $< 1/10$ ), uncommon ( $\geq 1/1,000$  to  $< 1/100$ ), rare ( $\geq 1/10,000$  to  $< 1/1,000$ ), very rare ( $< 1/10,000$ ), not known (cannot be estimated from the available data).

#### *Endocrine disorders*

Not known: Adrenal suppression (see section 4.4).

#### *Eye disorders*

Not known: Chorioretinopathy, vision blurred (see section 4.4).

#### *Gastrointestinal disorders*

Not known: Anorectal discomfort.

#### *Skin and subcutaneous tissue disorders*

Not known: Urticaria, rash (see section 4.4).

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

### **4.9 Overdose**

Not applicable to a product with this route of administration.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Agents for treatment of haemorrhoids and anal fissures for topical use - corticosteroids

ATC code: C 05 AA 01.

#### Hydrocortisone

The principle pharmacological actions of hydrocortisone are on gluconeogenesis, glycogen deposition, protein and calcium metabolism and inhibition of corticotrophin secretion and anti-inflammatory activity (glucocorticoid actions). When applied topically hydrocortisone causes reduction of inflammation, pruritus and exudation in disorders of the skin and perianal region.

#### Cinchocaine hydrochloride

Cinchocaine hydrochloride is a local anaesthetic agent and is suitable for surface or spinal anaesthesia and for relaxing sphincteric spasms. It is an anaesthetic of the amide type. It is more toxic than cocaine by local application, but its local anaesthetic action is greater, so it can be used in lower concentrations. Its action is more prolonged than lignocaine.

Surface or topical anaesthetics such as cinchocaine block the sensory nerve endings in the skin preventing transmissions of impulses along the nerve fibres and inhibiting depolarisation and ion-exchange. These effects are reversible. Before this blocking action can occur the lipid, soluble anaesthetic base must penetrate the lipoprotein nerve sheath and the effectiveness of the anaesthetic depends on the concentration attained in the nerve fibre. The onset of action varies depending on the anaesthetic used. Cinchocaine has a rapid onset of action and is also long lasting.

### **5.2 Pharmacokinetic properties**

#### Hydrocortisone

Hydrocortisone is passed through the skin, particularly in denuded areas. About 90% of plasma hydrocortisone is bound to plasma proteins, mainly to globulin, less so to

albumin. In the liver and most body tissues it is metabolised to hydrogenated and degraded forms such as tetrahydrocortisone and tetrahydrocortisol. These degraded forms are excreted in the urine. They are mainly conjugated as glucuronides. A very small proportion of unchanged hydrocortisone is excreted in the urine.

#### Cinchocaine hydrochloride

Most local anaesthetics such as cinchocaine hydrochloride are absorbed through damaged skin. Cinchocaine hydrochloride is an ester-type local anaesthetic. Following absorption, it is hydrolysed by esterases in the plasma and liver.

### **5.3 Preclinical safety data**

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Adeps Solidus (Witepsol H15) Ph. Eur.

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

18 months

### **6.4 Special precautions for storage**

Do not store above 25°C. Store in the original package.

### **6.5 Nature and contents of container**

Printed Aluminium Foil.

The product is available in packs of 10 and 12 suppositories.

Not all pack sizes may be marketed.

### **6.6 Special precautions for disposal**

Not applicable.

## **7 MARKETING AUTHORISATION HOLDER**

Chemidex Pharma Limited  
8a Crabtree Road  
Egham  
Surrey TW20 8RN  
United Kingdom

## **8 MARKETING AUTHORISATION NUMBER(S)**

PL 17736/0002

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

3 November 2000/ 5 March 2004

**10 DATE OF REVISION OF THE TEXT**

15/02/2025